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EXAMINER

TOMASZEWSKI, MICHAEL

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/864,926		NG ET AL.	
	Examiner		Art Unit	
	Mike Tomaszewski		3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>26 August 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice To Applicant

1. This communication is in response to the application filed on 24 May 2001. Claims 1-46 are pending. The IDS statements filed 26 August 2004, 25 August 2004, 24 August 2004, 8 March 2004, 13 August 2003, 11 July 2003, 17 January 2003, and 24 August 2001 have been entered and considered.

Claim Objections

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Examiner notes Applicant's acknowledgment that two different claims were inadvertently numbered "32" (i.e., Applicant's letter dated June 23, 2005). Insofar as Applicant has not corrected this discrepancy, Examiner has renumbered Applicant's

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claims accordingly. Misnumbered Claims 32-46 have been renumbered 33-47, respectively.

Examiner also notes that the preambles to Claims 39-41, 43, and 45, as drafted, appear to reference erroneous dependencies. For example, claim 39 states "The method of Claim 1 further comprising..." On the contrary, Claim 1 is a system claim rather than a method claim. Similar discrepancies exist with Claims 40-41, 43, and 45. In light of these discrepancies, Examiner has proceeded as though Applicant intended Claims 39-41 to depend from method claim 38, Claim 43 to depend from Claim 42, and Claim 45 to depend from Claim 44.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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4. Claims 1-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Fletcher-Haynes et al. (US 2001/0034614; hereinafter Fletcher-Haynes).

(A) As per Claim 1, Fletcher-Haynes discloses a system for managing a procedure in a blood component collection facility, the system comprising:

- (i) a blood component donor identifier corresponding to a blood component donor (Fletcher-Haynes: par. [0167]);
- (ii) a blood component collection instrument for collecting a blood component from the blood component donor (Fletcher-Haynes: par. [0056]), the blood component collection instrument having a blood component collection instrument identifier (Fletcher-Haynes: par. [0159]);
- (iii) a system server being operably connected to the blood component collection instrument (Fletcher-Haynes: par. [0065]), the system server running a blood component collection application defining at least a portion of a blood component collection process (Fletcher-Haynes: par. [0057]), the system server comprises a memory for storing the blood component donor identifier wherein the blood collection component application further associates the blood component donor identifier with the blood component collection instrument identifier (Fletcher-Haynes: par. [0057]); and
- (iv) a management interface having a reader and being operably connected to the system server for transmitting the blood component donor identifier

and the blood component collection instrument identifier to the system server (Fletcher-Haynes: par. [0059] and [0071]).

(B) As per Claim 2, Fletcher-Haynes discloses the system of Claim 1 further comprising:

a blood component collection kit for interfacing the blood component donor with the blood component collection instrument, the blood component collection kit having a blood component collection kit identifier wherein the blood component collection kit identifier can be transmitted to the system server for storing the blood component collection kit identifier in the memory and for associating the blood component collection kit identifier with the blood component donor identifier or the blood collection instrument identifier (Fletcher-Haynes: par. [0022], [0057], [0065], and [0125; Fig. 6A]; Examiner considers "tubing set" and/or "bag" to read on collection kit.).

(C) As per claim 3, Fletcher-Haynes discloses the system of Claim 2 further comprising:

an operator having an operator identifier wherein the operator communicates with the system server by utilizing the management interface to transmit the operator identifier to the system server for recording the operator's involvement with the blood component collection process (Fletcher-Haynes: par. [0012] and [0079]; Fig. 6D).

(D) As per claim 4, Fletcher-Haynes discloses the system of Claim 1 wherein the management interface utilizes radio frequency to transmit to the system server (Fletcher-Haynes: par. [0059]).

(E) As per Claim 5, Fletcher-Haynes discloses the system of Claim 1 further comprising:

- (i) a system communication conduit for operably connecting the system server to the blood component collection instrument (Fletcher-Haynes: par. [0012] and [0065]); and
- (ii) a system communication protocol for facilitating communication on the communication conduit between the system server and the blood component collection instrument (Fletcher-Haynes: par. [0030]).

(F) As per Claim 6, Fletcher-Haynes discloses the system of Claim 5 wherein the system communication protocol is the Internet (Fletcher-Haynes: par. [0066] and [0194]).

(G) As per Claim 7, Fletcher-Haynes discloses the system of Claim 5 wherein the system communication protocol is TCP/IP (Fletcher-Haynes: par. [0194]).

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(H) As per Claim 8, Fletcher-Haynes discloses the system of Claim 5 further comprising:

- (i) a network server being operably connected to the system server via a network communication conduit (Fletcher-Haynes: par. [0012] and [0065]); and
- (ii) a web interface being operably connected to the system server for facilitating access to the blood component collection process, wherein the management interface receives data from the system server (Fletcher-Haynes: par. [0033]).

(I) As per Claim 9, Fletcher-Haynes discloses the system of Claim 1 including a web server being operably connected to the system server and operably responsive to a web browser wherein the information stored in the system server can be accessed (Fletcher-Haynes: par. [0194]).

(J) As per Claim 10, Fletcher-Haynes discloses the system of Claim 3 wherein the reader comprises a touch pad for receiving the operator identifier, the blood component collection instrument identifier, the blood component collection kit identifier or the blood component donor identifier (Fletcher-Haynes: par. [0057]).

(K) As per Claim 11, Fletcher-Haynes discloses the system of Claim 3 wherein the reader comprises a keypad for receiving the operator identifier, the blood component

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collection instrument identifier, the blood component collection kit identifier or the blood component donor identifier (Fletcher-Haynes: par. [0059]; Examiner considers “keyboard” to read on keypad.).

(L) As per Claim 12, Fletcher-Haynes discloses the system of Claim 3 wherein the reader comprises an optical scanner for receiving the operator identifier, the blood component collection instrument identifier, the blood component collection kit identifier or the blood component donor identifier (Fletcher-Haynes: par. [0059]; Examiner considers a “barcode scanner” to be an example of an optical scanner.).

(M) As per Claim 13, Fletcher-Haynes discloses the system of Claim 3 wherein the reader comprises a magnetic scanner for receiving the operator identifier, the blood component collection instrument identifier, the blood component collection kit identifier or the blood component donor identifier (Fletcher-Haynes: par. [0059]).

(N) As per Claim 14, Fletcher-Haynes discloses a system for managing one or more procedures in a blood component collection facility, the system comprising:

- (i) a blood component collection instrument having a blood component collection instrument identifier (Fletcher-Haynes: par. [0056] and [0159]);
- (ii) a blood component collection kit having a blood component collection kit identifier (Fletcher-Haynes: par. [0022] and [0125]);

- (iii) a blood component donor identifier corresponding to a blood component donor (Fletcher-Haynes: par. [0167]);
- (iv) a management interface comprising a transmitter for transmitting a communication signal wherein the communication signal includes the blood component donor identifier (Fletcher-Haynes: par. [0059] and [0083]);
- (v) a receiver for receiving the communication signal from the management interface (Fletcher-Haynes: par. [0090]; Examiner notes that communication transmission occurring "both ways" necessitates the use of a receiver within the Fletcher-Haynes system.);
- (vi) a system server comprising an operating system being operably responsive to the blood component collection instrument and the management interface, the operating system being capable of compiling the blood component donor identifier, the blood component collection instrument and the blood component collection kit and associating the blood component collection kit with each other (Fletcher-Haynes: par. [0012]; Fig. 1-6I); and
- (vii) a communication conduit operably interfacing the system server with the blood component collection instrument wherein the operating system monitors a blood component collection procedure (Fletcher-Haynes: par. [0012]).

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(O) As per Claim 15, Fletcher-Haynes discloses the system of Claim 14 further comprising:

an operator having an operator identifier wherein the operator interacts with the system server by utilizing the management interface to transmit the operator identifier to the system server for recording the operator's involvement with a blood component collection process (Fletcher-Haynes: par. [0012] and [0079]; Fig. 6D).

(P) As per Claim 16, Fletcher-Haynes discloses the system of Claim 14 further comprising:

- (i) a web interface being operably connected to the system server for facilitating access to the system server (Fletcher-Haynes: par. [0033]);
- (ii) a network server being operably connected to the system server via the communication conduit (Fletcher-Haynes: par. [0012] and [0065]); and
- (iii) a communication protocol for facilitating communication on the communication conduit between the system server and the network server (Fletcher-Haynes: par. [0030] and [0066]).

(Q) As per Claim 17, Fletcher-Haynes discloses the system of Claim 16 wherein the communication protocol is Ethernet (Fletcher-Haynes: par. [0030]).

(R) As per Claim 18, Fletcher-Haynes discloses the system of Claim 16 wherein the communication protocol is TCP/IP (Fletcher-Haynes: par. [0194]).

(S) As per Claim 19, Fletcher-Haynes discloses the system of Claim 14 wherein the communication signal is a radio frequency (Fletcher-Haynes: par. [0059] and [0064]).

(T) As per Claim 20, Fletcher-Haynes discloses the system of Claim 14 wherein the management interface comprises a receiver and a communication signal transmitted from the system server, the received wireless communication signal providing blood component collection facility information (Fletcher-Haynes: par. [0059], [0083] and [0090]).

(U) As per Claim 21, Fletcher-Haynes discloses the system of Claim 14 wherein the management interface comprises a reader for entering a blood component collection facility identifier (Fletcher-Haynes: par. [0071]).

(V) As per Claim 22, Fletcher-Haynes discloses the system of Claim 21 wherein the reader for entering comprises a touch pad for receiving the operator identifier, the blood component collection instrument identifier or the blood component donor identifier (Fletcher-Haynes: par. [0057]).

(W) As per Claim 23, Fletcher-Haynes discloses the system of Claim 21 wherein the reader for entering comprises a keypad for receiving the operator identifier, the blood

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component collection instrument identifier or the blood component donor identifier
(Fletcher-Haynes: par. [0059]).

(X) As per Claim 24, Fletcher-Haynes discloses the system of Claim 21 wherein the reader for entering comprises an optical scanner for receiving the operator identifier, the blood component collection instrument identifier or the blood component donor identifier
(Fletcher-Haynes: par. [0059]).

(Y) As per Claim 25, Fletcher-Haynes discloses the system of Claim 21 wherein the reader for entering comprises a magnetic scanner for receiving the operator identifier, the blood component collection instrument or the blood component donor identifier
(Fletcher-Haynes: par. [0059]).

(Z) As per Claim 26, Fletcher-Haynes discloses a method for managing one or more procedures in a blood component collection facility, the method comprising the steps of:

- (i) providing a blood component collection instrument (Fletcher-Haynes: par. [0056]);
- (ii) providing a system server having an operating system and a memory, the system server defining a blood component collection process and being operably connected to the blood component collection instrument
(Fletcher-Haynes: par. [0012] and [0059]);

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- (iii) providing a blood component donor identifier correlating to a blood component donor (Fletcher-Haynes: par. [0167]);
- (iv) transmitting the blood component donor identifier to the system server (Fletcher-Haynes: par. [0012] and [0059]);
- (v) storing the blood component donor identifier in the memory (Fletcher-Haynes: par. [0012] and [0059]); and
- (vi) associating the blood component donor identifier with the blood component collection instrument (Fletcher-Haynes: Fig. 6A)

(AA) As per Claim 27, Fletcher-Haynes discloses the method of Claim 26 further comprising:

- (i) providing a blood component collection kit having a blood component collection kit identifier (Fletcher-Haynes: par. [0022] and [0125]);
- (ii) transmitting the blood component collection kit identifier to the system collection kit identifier (Fletcher-Haynes: par. [0012]);
- (iii) storing the blood component collection kit identifier in the memory (Fletcher-Haynes: par. [0012] and [0059]); and
- (iv) associating the blood component donor identifier with the blood component collection kit (Fletcher-Haynes: Fig. 6A).

(BB) As per Claim 28, Fletcher-Haynes discloses the method of Claim 27 further comprising:

- (i) providing an operator identifier associated with an operator (Fletcher-Haynes: par. [0079]);
- (ii) transmitting the operator identifier to the system server to indicate the operator's involvement with a blood component collection procedure (Fletcher-Haynes: par. [0012]).

(CC) As per Claim 29, Fletcher-Haynes discloses the method of Claim 28 further comprising:

- (i) providing a communication conduit (Fletcher-Haynes: par. [0012]);
- (ii) providing a network server being operably connected to the system server via the communication conduit (Fletcher-Haynes: par. [0065]);
- (iii) providing a communication protocol for facilitating communication on the communication conduit between the system server and the network server (Fletcher-Haynes: par. [0066] and [0194]); and
- (iv) displaying information associated with the blood component donor identifier and stored in the memory of the system server (Fletcher-Haynes: par. [0012]; Fig. 6A).

(DD) As per Claim 30, Fletcher-Haynes discloses the method of Claim 29 further comprising:

providing a web server being operably connected to the system server for allowing access to the information stored on the system server (Fletcher-Haynes: par. [0194]).

(EE) As per Claim 31, Fletcher-Haynes discloses a method for managing one or more procedures in a blood component collection facility, the method comprising the steps of:

- (i) providing a blood component collection instrument having a blood component collection instrument identifier (Fletcher-Haynes: par. [0056]);
- (ii) providing a system server having an operating system and a memory, the system server being operably connected to the blood component collection instrument (Fletcher-Haynes: par. [0057] and [0065]);
- (iii) providing a blood component donor identifier, the blood component donor identifier being assigned to a blood component donor (Fletcher-Haynes: par. [0167]);
- (iv) providing a management interface having a reader and being operably connected to the system server (Fletcher-Haynes: par. [0059] and [0167]);
- (v) reading the blood component donor identifier into the management interface (Fletcher-Haynes: par. [0071]);
- (vi) transmitting the blood component donor identifier into the management interface (Fletcher-Haynes: par. [0012] and [0059]);
- (vii) storing the blood component donor identifier within the memory (Fletcher-Haynes: par. [0012] and [0059]).

(FF) As per Claim 32, Fletcher-Haynes discloses the method of Claim 31 further comprising:

- (i) assessing a biological characteristic of the blood component donor (Fletcher-Haynes: Fig. 2C, 2D and 3C);
- (ii) transmitting the biological characteristic to the system server (Fletcher-Haynes: par. [0012]);
- (iii) storing the biological characteristic in the system server (Fletcher-Haynes: par. [0012]);
- (iv) associating the blood component donor identifier with the blood component collection identifier (Fletcher-Haynes: Fig. 6A);
- (v) calculating a blood component donor nomogram in response to the biological characteristic (Fletcher-Haynes: par. [0127] and [0296]; Fig. 3C and 9A-10);
- (vi) storing the blood component donor nomogram in the memory (Fletcher-Haynes: par. [0127]; Fig. 3C); and
- (vii) associating the blood component donor nomogram with the donor identifier (Fletcher-Haynes: par. [0127]; Fig. 3B and 3C).

(GG) As per Claim 33, the Fletcher-Haynes system includes a server, data storage devices, hardware, software and software. As such, it is readily apparent that a

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computer program stored on a computer-readable medium controls the Fletcher-Haynes system.

Moreover, Fletcher-Haynes discloses a medium readable by a computer, the medium having an operating interface for managing a blood component collection facility comprising an operator having an operator identifier, a blood component collection instrument, a blood component collection kit and a system server having a memory and being operably connected to the blood component collection instrument wherein the blood component collection facility cooperates with a blood component donor having a blood component donor identifier, the medium comprising:

- (i) a first segment for entering a blood component donor identifier (Fletcher-Haynes: par. [0012]);
- (ii) a second segment for storing the blood component donor identifier in a system server (Fletcher-Haynes: par. [0012] and [0059]);
- (iii) a third segment for entering an operator identifier (Fletcher-Haynes: par. [0079]);
- (iv) a fourth segment for storing the operator identifier in the system server (Fletcher-Haynes: par. [0012]);
- (v) a fifth segment for storing an interaction of the blood component donor with the blood component collection facility (Fletcher-Haynes: Fig. 4A and 5A; Examiner notes that the Fletcher-Haynes system stores various information pertaining to the collection devices, such as their network and physical locations. Moreover, the Fletcher-Haynes system stores

- interaction information between the donor and a particular collection machine. Coupling this knowledge together provides interaction information between a donor and a particular collection facility.); and
- (vi) a sixth segment for storing an interaction of the operator with the blood component collection facility (Fletcher-Haynes: par. [0012]).

(HH) As per Claim 34, further comprising:

- (i) a seventh segment for receiving a biological characteristic of the blood component donor (Fletcher-Haynes: Fig. 2C, 2D and 3C);
- (ii) a eighth segment for storing the biological characteristic (Fletcher-Haynes: par. [0012]); and
- (iii) a ninth segment for associating the biological characteristic with the blood component donor (Fletcher-Haynes: Fig. 6A).

(II) As per Claim 35, Fletcher-Haynes discloses the medium of Claim 33 further comprising:

- (i) a tenth segment for calculating a blood component donor nomogram in response to the biological characteristic (Fletcher-Haynes: par. [0127] and [0296]; Fig. 3C and 9A-10);
- (ii) an eleventh segment for storing the blood component nomogram (Fletcher-Haynes: par. [0127]; Fig. 3C); and

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- (iii) a twelfth segment for associating the blood component donor nomogram with the blood component donor identifier (Fletcher-Haynes: par. [0127]; Fig. 3B and 3C).

(JJ) As per Claim 36, Fletcher-Haynes discloses the medium of Claim 34 further comprising:

- (i) a thirteenth segment for storing an interaction of the operator with a blood component collection instrument (Fletcher-Haynes: par. [0012] and [0079]);
- (ii) a fourteenth segment for storing an interaction of the blood component donor with the blood component collection instrument (Fletcher-Haynes: par. [0012]); and
- (iii) a fifteenth segment for storing an interaction of the operator with the blood component donor (Fletcher-Haynes: [0012]).

(KK) As per Claim 37, Fletcher-Haynes discloses the medium of Claim 35 further comprising:

- (i) a sixteenth segment for generating a report responsive to the compilation of blood component collection facility information stored in the memory wherein statistics, trends and details on the blood component collection facility can be obtained (Fletcher-Haynes: par. [0012]).

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(LL) As per Claim 38, Fletcher-Haynes discloses the medium of Claim 36 further comprising:

a seventh segment for displaying blood component collection facility information (Fletcher-Haynes: Fig. 5A and 6D).

(MM) As per Claim 39, Fletcher-Haynes discloses a method of configuring a blood component collection instrument comprising the steps of:

- (i) collecting a biological characteristic of a donor (Fletcher-Haynes: Fig. 2C, 2D and 3C);
- (ii) calculating a nomogram by utilizing the biological characteristic of the donor (Fletcher-Haynes: par. [0127] and [0296]; Fig. 3C and 9A-10);
- (iii) transmitting the nomogram to a blood component collection instrument (Fletcher-Haynes: par. [0012]);
- (iv) selecting a blood component collection application in response to the nomogram, the blood component collection application defining at least a portion of a blood component collection process (Fletcher-Haynes: par. [0012], [0057] and [0059]); and
- (v) loading the selected blood component collection application wherein the blood component collection instrument is configured for the blood component collection process involving the donor (Fletcher-Haynes: par. [0014] and [0015]; Fig. 6A).

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(OO) As per Claim 40, Fletcher-Haynes discloses the method of Claim 39 further comprising the steps of:

- (i) providing a memory being capable of storing a plurality of blood component collection applications (Fletcher-Haynes: par. [0012]); and
- (ii) providing a server for running the blood component collection process, the server being operably connected to the blood component collection instrument and the memory (Fletcher-Haynes: par. [0012]).

(PP) As per Claim 41, Fletcher-Haynes discloses the method of Claim 40 further comprising the steps of:

providing a management interface for transmitting the nomogram to the system server (Fletcher-Haynes: par. [0059]).

(QQ) As per Claim 42, Fletcher-Haynes discloses the method of Claim 40 further comprising the steps of:

- (i) providing an identifier for the donor (Fletcher-Haynes: par. [0167]);
- (ii) associating the nomogram with the donor identifier (Fletcher-Haynes: par. [0127]; Fig. 3B and 3C); and
- (iii) storing the nomogram in the memory (Fletcher-Haynes: par. [0127]; Fig. 3C).

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(RR) As per Claim 43, Fletcher-Haynes discloses a method of configuring a blood component collection instrument comprising the steps of:

- (i) providing a blood component collection application defining at least a portion of a blood component collection process (Fletcher-Haynes: par. [0012];
- (ii) providing a memory being capable of storing a plurality of blood component collection applications (Fletcher-Haynes: par. [0012]);
- (iii) collecting a biological characteristic of a donor (Fletcher-Haynes: Fig. 2C, 2D and 3C);
- (iv) calculating a nomogram by utilizing the biological characteristic of the donor, the donor having an identifier (Fletcher-Haynes: par. [0127] and [0296]; Fig. 3C and 9A-10);
- (v) associating the nomogram with the donor identifier (Fletcher-Haynes: par. [0127]; Fig. 3B and 3C);
- (vi) storing the donor identifier in the memory (Fletcher-Haynes: par. [0057]);
- (vii) transmitting the donor identifier to the blood component collection instrument (Fletcher-Haynes: par. [0057]);
- (viii) retrieving the nomogram associated with the donor identifier (Fletcher-Haynes: par. [0127]; Fig. 3B and 3C);
- (ix) selecting a blood component collection application in response to the nomogram (Fletcher-Haynes: par. [0012], [0057] and [0059]);

- (x) loading the selected blood component collection application (Fletcher-Haynes: par. [0057]); and
- (xi) providing a server for running the blood component collection process, the server being operably connected to the blood component collection instrument and the memory (Fletcher-Haynes: par. [0012]).

(SS) As per Claim 44, Fletcher-Haynes discloses the method of Claim 43 further comprising the step of:

providing a management interface for transmitting the nomogram to the system server (Fletcher-Haynes: par. [0059]).

(TT) As per Claim 45, Fletcher-Haynes discloses a system for configuring a blood component collection instrument, the blood component collection instrument being operably connected in a blood component collection facility for collecting a blood component from a donor, the system comprising:

- (i) a nomogram calculated from at least one biological characteristic of a donor (Fletcher-Haynes: par. [0127] and [0296]; Fig. 3C and 9A-10);
- (ii) a blood component collection application defining at least a portion of a blood component collection process (Fletcher-Haynes: par. [0012]);
- (iii) a system server being operably connected to the blood component collection instrument, the system server running the blood component collection application, the blood component collection application being

selected in response to the nomogram (Fletcher-Haynes: par. [0012], [0057] and [0059]) wherein the blood component collection instrument is configured for the blood component collection process from the donor (Fletcher-Haynes: par. [0012]); and

- (iv) a memory being operably connected to the system server, the memory for storing the blood component collection application (Fletcher-Haynes: par. [0012]).

(UU) As per Claim 46, Fletcher-Haynes discloses the system of Claim 45 further comprising:

a reader for entering the nomogram, the reader being operably connected to the system server wherein the nomogram is associated with the donor (Fletcher-Haynes: par. [0022] and [0071]).

(VV) As per Claim 47, the Fletcher-Haynes system includes a server, data storage devices, hardware, software and software. As such, it is readily apparent that a computer program stored on a computer-readable medium controls the Fletcher-Haynes system.

Moreover, Fletcher-Haynes discloses a medium readable by a programmable device, the medium having an operating interface for managing a blood component collection facility comprising a blood component collection instrument and a system server, the system server having a memory and being operably connected to the blood

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component collection instrument, the blood component collection instrument being capable of self-configuring the blood component collection instrument in response to a nomogram received by the system server, the nomogram being calculated in response to a biological characteristic of an identified donor, the medium comprising:

- (i) a first segment for receiving the nomogram (Fletcher-Haynes: par. [0127]; Fig. 3C);
- (ii) a second segment for selecting a blood component collection application in response to the nomogram (Fletcher-Haynes: par. [0012], [0057] and [0059]);
- (iii) a third segment for loading the blood component (Fletcher-Haynes: Fig. 3D); and
- (iv) a fourth segment for configuring the blood component collection instrument in response to the blood component collection application, the configured blood component collection instrument being ready for blood component collection from the donor (Fletcher-Haynes: par. [0014]).

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied art teaches a method and apparatus for determining at least one unknown data of a biological fluid (3,654,445); a nomogram

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for calculating the maximum tolerable blood loss of a patient (D298,651); an apheresis method and device (5,112,298); a blood sample and method (5,316,952); a feedback controlled drug delivery system (5,697,899); a diagnostic assay system (US2002/0055176); immunotherapeutic methods for extracorporeal modulation of CD36 and its ligands (US2002/0086276); rheological treatment methods and related apheresis systems (6,551,266); and a blood glucose tracking apparatus and methods (US2003/0176183).

The cited but not applied prior art also includes non-patent literature articles by Meaney, Eduardo; Alva, Felix; Moguel, Rafael; and Meaney, Alejandra ("Formula and Nomogram for the Sphygmomanometric Calculation of the Mean Arteri..." Jul. 2000. Health & Medical Complete. pg. 64.) and Bruno, Lee ("Doctors Start to Log On As Patient Records Go Electronic" Jan. 19, 1996. San Francisco Business Times. pg. 1.).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Tomaszewski whose telephone number is (571)272-8117. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571)272-6776. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


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7.14.05


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